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TITLE: A Treatment Stage Specific Approach to Improving Quality of Life for Women with Ovarian Cancer

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14. ABSTRACT Our primary objective is to identify the issues that are of greatest concern to women in each of three treatment stages: newly diagnosed with ovarian cancer, in-treatment, and post-treatment. A longitudinal, repeated measures design will be used to assess changes in problem areas and quality of life from diagnosis to recurrence among women newly diagnosed with ovarian cancer. The CARES-SF and FACT-O questionnaires will be administered to participants following diagnosis and prior to chemotherapy, during chemotherapy, following chemotherapy, and after recurrence. Data collection for the study will last 28 months (patient accrual will last 25 months and follow-up will continue an additional 3 months). Data for the study will be collected through in-person interviews, and mailed questionnaires (with possible telephone follow-up) from women treated at the Wake Forest University Baptist Medical Center (WFUBMC) and Forsyth Medical Center (FMC).					
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Table of Contents

Cover.....	1
SF 298.....	2
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	6
Reportable Outcomes.....	7
Conclusions.....	7
References.....	7

PART I - INTRODUCTION

This study focuses on quality of life among women with ovarian cancer. The primary objective is to identify the issues that are of greatest concern to women in each of three treatment stages: newly diagnosed with ovarian cancer, in-treatment, and post-treatment. A longitudinal, repeated measures design is being used to assess changes in problem areas and quality of life from diagnosis to recurrence among women newly diagnosed with ovarian cancer. The CARES-SF and FACT-O questionnaires are administered to participants following diagnosis and prior to chemotherapy, during chemotherapy, following chemotherapy, and after recurrence.

Data collection for the study will last 28 months (patient accrual will last 25 months and follow-up will continue an additional 3 months). Data for the study are collected through in-person interviews, and mailed questionnaires from women treated at the Wake Forest University Baptist Medical Center (WFUBMC) and Forsyth Medical Center (FMC).

Secondary objectives are of the study: 1) to assess changes in quality of life (as quantified by the FACT-O questionnaire) across the different stages of care, 2) to determine which patient characteristics are predictive of quality of life at each treatment stage, 3) to determine which patient characteristics are predictive of changes in quality of life across the different treatment stages, and 4) to obtain pilot data on problems and quality of life issues for women who experience a recurrence.

PART II – BODY: STATEMENT OF WORK

The primary activities during the first year of the study were to obtain Human Subjects Protection approval from the Department of Defense, finalize study forms, and pilot the study. In August 2002 study recruitment began, but we quickly realized that we needed to change the procedure for questionnaire administration. We realized that instead of having patients complete baseline questionnaires while they were still in the hospital, it would be better to have these questionnaires mailed to patients after their discharge. A request to change the protocol was submitted to HSRRB in September 2002, but we did not receive approval for this change until May 16, 2003. Therefore, much of the time during the current reporting period was spent waiting for approval from HSRRB for our change in protocol. This delay had a significant impact on our recruitment and ability to conduct the study within the specified timeframe.

During the time we were waiting for the above approval, it also became clear that we needed to add an additional study site. We contacted Forsyth Medical Center (FMC) and they were agreeable to becoming a site. The protocol and study forms were submitted to FMC IRB on 2/13/03 and were approved on 3/14/03. The protocol amendment to request this additional site was then submitted to the Office of Human Subjects Protection on 3/14/03, but additional information was requested. By May 2003 all required documents were submitted to HSRRB. February 2004 we finally received approval to recruit at Forsyth.

We are still concerned about recruiting sufficient numbers of patients to the study. We are learning that while patients are still in hospital are not the best times to recruit. By expanding the time frame to allow recruitment of women with newly diagnosed ovarian cancer to be recruited up to a month past discharge from the hospital, we will have more opportunity to recruit women into the study. In order to be able to still address the primary research questions of the grant, we also requested to recruit women at any stage post diagnosis. In addition to

recruiting women who are newly diagnosed, we will recruit women who are in treatment, post-treatment, or have had a recurrence that we may have previously missed. All documentation for these protocol amendments was submitted to the WFUBMC IRB on 8/21/05 and approval was granted on 9/23/05. This request for these protocol changes was then sent to the Office of Human Subjects Protection on 9/28/05 and is still under review.

The tasks described in the original statement of work have not changed. However, time involved in obtaining Human Subjects approval from the Department of Defense was not included as part of the original timeline. These approvals have taken an enormous amount of time and have essentially moved the timeline back over almost two years. We have recently received a 1 year no cost extension of the project.

Task 1: Develop research protocol (months 1-2)

a. Compile open-ended questions, relevant questionnaires, and sociodemographics in an interview format

The questionnaires have been compiled and approved by the WFUSM and the FMC IRBs.

b. Train study interviewer

The study interviewer has been hired and trained. The project director has also been hired and trained to serve as a back-up interviewer.

c. Pilot test interview with patients

We pilot tested the interview on 5 participants.

d. Finalize questionnaire based on pilot

The study questionnaire was finalized after the pilot.

Task 2: Develop data management system (months 1-2)

- a. Develop data management requirements
- b. Develop reporting requirements
- c. Develop contact record
- d. Train research staff to use DMS

The above tasks have all been completed.

Task 3: Identify, recruit, and interview patients who meet eligibility criteria (months 3-40)

- a. Identify eligible patients
- b. Recruited and interview patients
- c. Conduct quality control of interviews (ongoing)

To date, 49 patients have been recruited into the study.

- d. Develop data entry system
A data entry system is currently underdevelopment
- e. Transcribe and code open-ended interviews (ongoing)
- f. Abstract clinical data from charts
The abstraction of clinical data is ongoing
- g. Data entry of questionnaires (ongoing)

Tasks f and g have not yet begun

Task 4: Ongoing Follow-up of Patients (months 6-40)

- a. Track women previously interviewed
- b. Interview women at appropriate treatment stages
- c. Interview recurrent cases

We have begun follow-up of women at appropriate stages. We have not had any recurrent cases. There have been two participant deaths.

Task 5: Data analysis and report writing (months 41-48)

- a. Transfer data into SAS
- b. Clean data and generate codebooks
- c. Analyze data from interviews
- d. Present results at professional meeting
- e. Prepare initial manuscripts

Task 5 has not yet begun

Task 6: Develop interventions that can be tested in future research (month 36)

- a. Review findings and develop ideas for interventions
- b. Plan interventions for future trials

Task 6 has not yet begun

PART III - KEY RESEARCH ACCOMPLISHMENTS

- Finalization of study forms
- Obtaining human subjects protection approval
- Recruitment of an additional study site

None

PART IV - REPORTABLE OUTCOMES

None

PART V - CONCLUSIONS

This section is not applicable at this point.

PART VI - REFERENCES

Not applicable